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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,483	10/12/2000	Kevin H. Storm	P32685	9497

20462 7590 09/13/2006

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EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/689,483

Applicant(s)

STORM ET AL.

Examiner

NEIL LEVY

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13, 18 and 69-235 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 18, 69-235 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12-22-03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claim 78-85, 93-168, 230-235 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language used is not standard Markush, "...from the group consisting of..." and thus it is unclear if in 78-85, 231, 233, 235 salts refer to the last compound listed, or to all. The "and" of claim 230-235 adds further confusion. claim 121 needs an "in".

#### ***Double Patenting***

Claims 204, 209 – 213 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6136345 or 6358528 to Grimm et al, in view of PDR and Bax 6214359..

There is no acid required in the instant claims, Although the conflicting claims are not identical, they are not patentably distinct from each other because Grimm shows the instant tablets, but not their use, except in general. PDR delineates use, while Bax shows equivalence of amoxicillin forms.

Claim 13, 18, 69-130, 141-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 13, 15-19, 21, 23-44, 60, 61, 68-80 of U.S. Patent No. 675605. Although the conflicting claims are not identical, they are not patentably distinct from each other because The patent claims are to the instant dosage forms, of the same materials and ratios of ingredients, so would provide the same results, thus are self evident to the artisan, even though the claim language differs as to the specific amounts and parameters of effects recited. Determination of specific amounts and ratios of ingredients would be a function of the sex, age, size and species of patient.

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Claims 13,70-205,219-235 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 09/681055. Although the conflicting claims are not identical, they are not patentably distinct from each other because The tablets of the patent provide the instant formulations intended.

. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 6/22/06 have been fully considered but they are not persuasive. Applicant's amendments have generated new rejection and continued rejection, but where persuasive, have resulted in withdrawal of rejections of 2/22/06 office action.

Applicant's arguments regarding rejection over GRIMM are persuasive, the double patenting rejection is withdrawn, as to the 20:1 to 1:2 ratios, but not over claim 204. The 102 rejections over GRIMMETT are also withdrawn, as are that over BURCH.

Claim 205, if amended to include claim 223 acids and claim 156 release excipients, would be allowable over the art of record.

. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

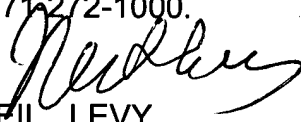
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
NEIL LEVY  
Primary Examiner  
Art Unit 1615

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